



Medtronic

15011
P-1113800
MCS

INVENTION DISCLOSURE FORM

WARNING: Due to the confidential nature of this document, save it as a password protected document. Do not send this document through GroupWise.

This is a WORD Template form. Press enter or tab to move to each field. Please fill out this form as completely as possible. If the allotted space is not sufficient, use a separate sheet. Have your manager sign the form and forward it to the Patent Section of the Law Department, MS301. Please attach any drawings and technical descriptions that are available and assemble copies of the background articles, books, advertisements, etc. for use by your patent attorney.

1.

Inventor(s)	Employee	Mail	Home Address (Include Zip Code)
Full Name(s)	Number	Stop	
Douglas Stephen Hine	13745	B230	3647 Willow Lane White Bear Lake MN 55110
John Louis Sommer	2380	B252	12788 Ibis Street NW, Coon Rapids, MN 55448
Dr John Gurley	N/A	N/A	
2. Title of Invention: Pacing lead with multiple electrodes having one IS-1 compatible connector pin
3. Summary of the Invention: This invention covers a pacing lead design with multiple electrodes on a lead having one connector pin that fits into any IS-1 header cavity. This invention offers multiple pacing and sensing options (selectable electrodes) with various polarity configurations for programming a device for optimal threshold performance, optimal sensing performance, eliminating phrenic nerve stimulation, or optimizing device therapy. An electrode pair is selected at implant during routine pacing tests (threshold, sensing, phrenic nerve stim) by using alligator clips on two of the four exposed connector rings. The connector pin is smaller in diameter than IS-1 and segmented such that each of the four exposed rings is connected to a distal electrode. Once a pair is selected, a metallic cap (IS-1 size) is placed over the smaller segmented connector pin. When the cap is placed over the segmented pin, it insulates two of the segments and makes electrical contact with the other two segmented rings. This creates a bipolar arrangement. The metallic IS-1 cap can be removed at a later date and replaced with a different IS-1 cap to "select" a different bipole. Before today, this could not be done with one IS-1 compatible connector pin. This could have multiple applications including left heart right heart and epicardial pacing systems.
4. How have others addressed this problem (List and attach any patents, books, articles, devices, Medtronic or competitor's products, or other background materials you used or which may be prior art)? Guidant has done studies on multi polar LV electrode design. However, it appears to be an acute study only without IS-1 compatibility. This could be done using a split connector having two IS-1 connectors.
5. The invention is described on pages 7-10 of Lab Notebook No. 10672 (Please attach copy).
6. When was a device built which included the invention? NA
Who built it? NA Where is it? NA
Who has supporting documents? NA
Who witnessed tests? NA When and where? NA
7. Discuss the problems which the invention is designed to solve, referring to any prior devices of a similar nature with which you may be familiar. This concept addresses the issue
8. State the advantages of the invention over presently known devices, systems or processes. This invention allows one lead to be used with one connector pin that fits into any IS-1 header. This allows universal use of a selectable bipole lead with today's pacing systems. No change to the pacing generator header or circuitry is needed.
9. List all known and other possible uses for the invention. Pacing and sensing, including left heart, right heart, epicardial leads.
10. Specifically describe the invention and its operation. You may use and attach copies of sketches, prints, photographs and illustrations which should be signed, witnessed and dated. Use numbers and descriptive names in descriptions and drawings. See attached lab notebook pages.

<http://intranet4.corp.medtronic.com/legal>

EXHIBIT B

11. List all features of the invention that are believed to be novel. Selectable electrodes on a lead having one IS-1 compatible connector pin. An IS-1 connector pin cap that can be placed over a segmented pin that allows selectable electrodes at implant or during repositioning.
12. Sale or Publication (Needed to establish the date of any printed publication, public use or sale, since no U. S. patent application may be filed after one year from such date.)
- a. If a device has been offered, or will be offered for sale, or used for profit or otherwise publicly disclosed, state when and to whom delivered and how used? _____
- b. Has a printed description of this invention been made available to persons outside the company? How and when and was use restricted (e.g. licensing agreement, non-disclosure agreement, proprietary legends, etc.)? Dr. John Gurley is a co-inventor. It was discussed with him on July 9, 2002 at an offsite meeting.

13. Inventor(s) Signature(s) (REQUIRED):

John L Sommer
Signature _____

29 July 02
Date _____
15 Oct 02

14. OR MULTIPLE ELECTRODE Manager's Comments
How is this invention important to your products, plans or goals?

MULTIPOLAR CONFIGURATIONS MAY PLAY AN IMPORTANT ROLE IN HF - CRT IN THE NEAR & LONG TERM FUTURE. THIS INVENTION ALLOWS SELECTION OF POLARITY CONFIGURATIONS W/O CHANGES TO DEVICE

15. Manager's Signature (REQUIRED)

Jack German
Signature _____

31 OCT 2002
Date _____

Manager's Printed Name Jack German

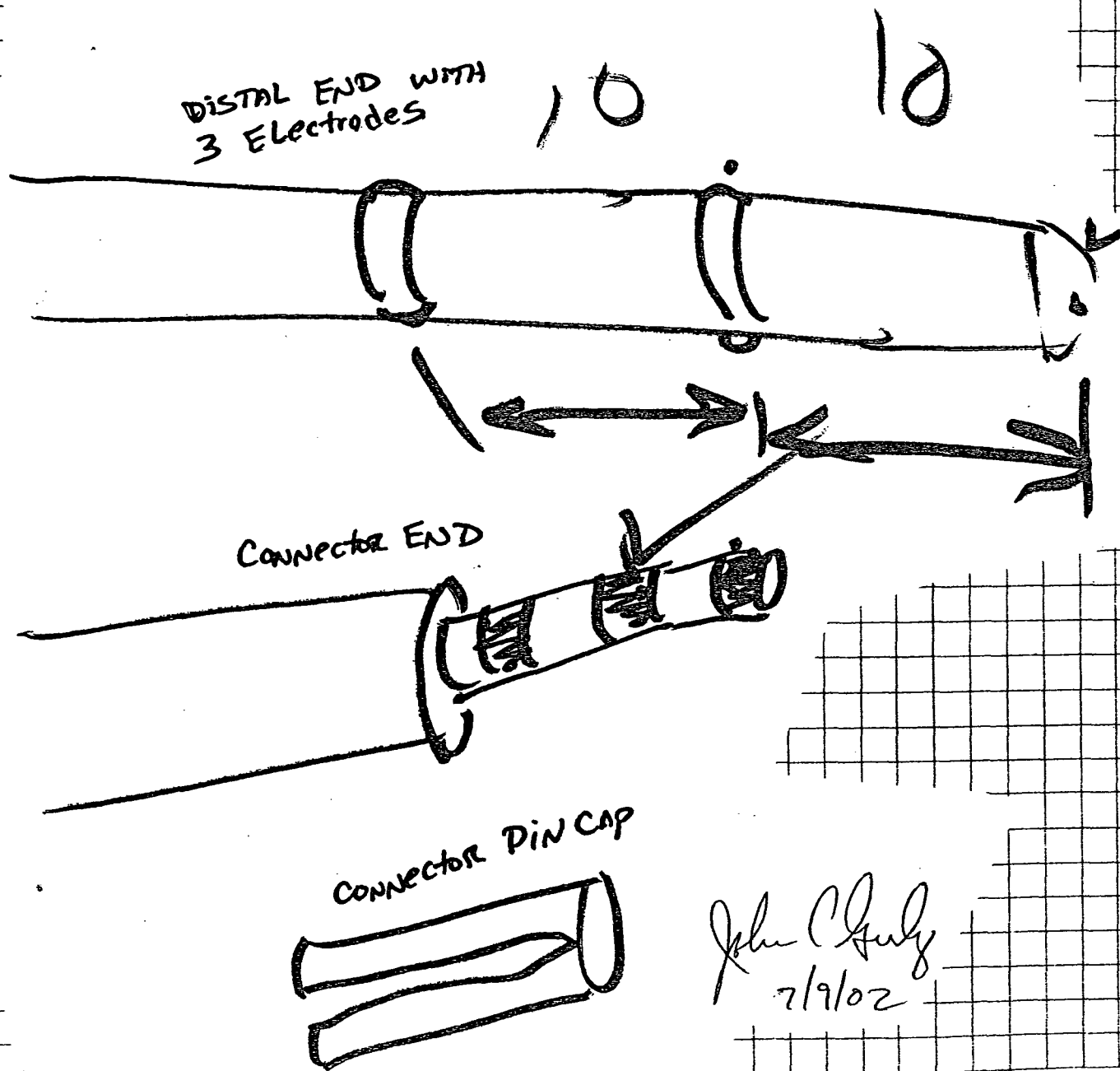
Mail Stop B230

Business Unit Cardiac Rhythm Management Therapy Delivery

Manager: Please forward to Patent Section of Law Department, MS 301, upon completion of your review.

TITLE PACING LEAD WITH Multiple Electrodes having Project No. _____
ONE IS-1 COMPATIBLE CONNECTOR PIN Book No. 10672

From Page No. _____



Witnessed & Understood by me, _____

Date _____

Invented by _____

Date _____

Recorded by _____

15 July 02

Page No. _____

From Page No. 7

Purpose: TO INVENT A LEAD WITH Multiple electrodes at its DISTAL TIP. A multi-conductor COIL WITH EACH FILAR INDEPENDENTLY INSULATED IS USED TO CONNECT THE electrodes TO ONE TERMINATION PIN. THIS PIN IS SEGMENTED SUCH THAT ANY PAIR OF electrodes CAN BE SELECTED AND TESTED FOR PACING AND SENSING. ONCE AN OPTIMAL PAIR IS FOUND, A METALLIC IS-1 CAP IS PLACED OVER THE SEGMENTED TERMINATION PIN. THIS CAP WILL BE IN ELECTRICAL CONTACT WITH TWO OF THE SEGMENTS OF THE TERMINATION PIN WHILE INSULATING THE OTHER TWO SEGMENTS.

BENEFIT: THIS INVENTION ALLOWS THE PHYSICIAN TO SELECT ONE electrode PAIR THAT PROVIDES THE optimal PACING performance, eg. GOOD THRESHOLDS FOR PACING, GOOD SENSING, NO PHRENIC NERVE STIMULATION AND OPTIMIZED CARDIAC RESYNCHRONIZATION THERAPY. THIS DESIGN ALLOWS A Multiple electrode LEAD TO BE "SELECTABLE" WHILE STILL BEING IS-1 COMPATIBLE

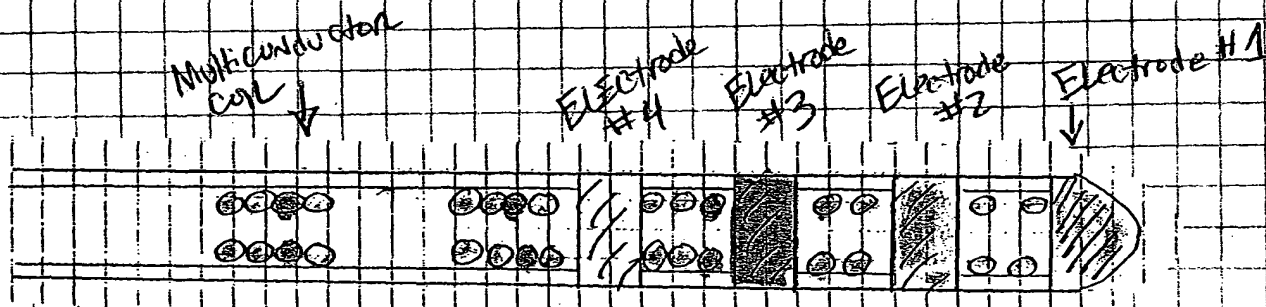


FIGURE 1, DISTAL TIP OF Multi-electrode lead

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Date

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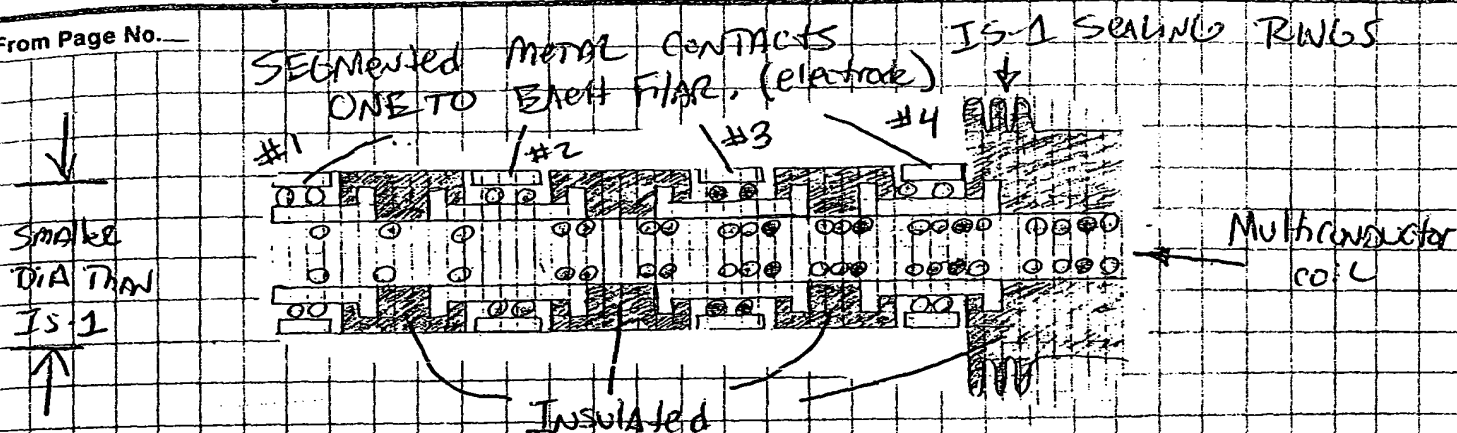


FIGURE #2. SEGMENTED termination PIN

CHOOSING ONE OF THE FOLLOWING IS-1 termination PIN CAPS will provide the desired electrode pairs. Four combinations ARE POSSIBLE AS SHOWN BELOW.

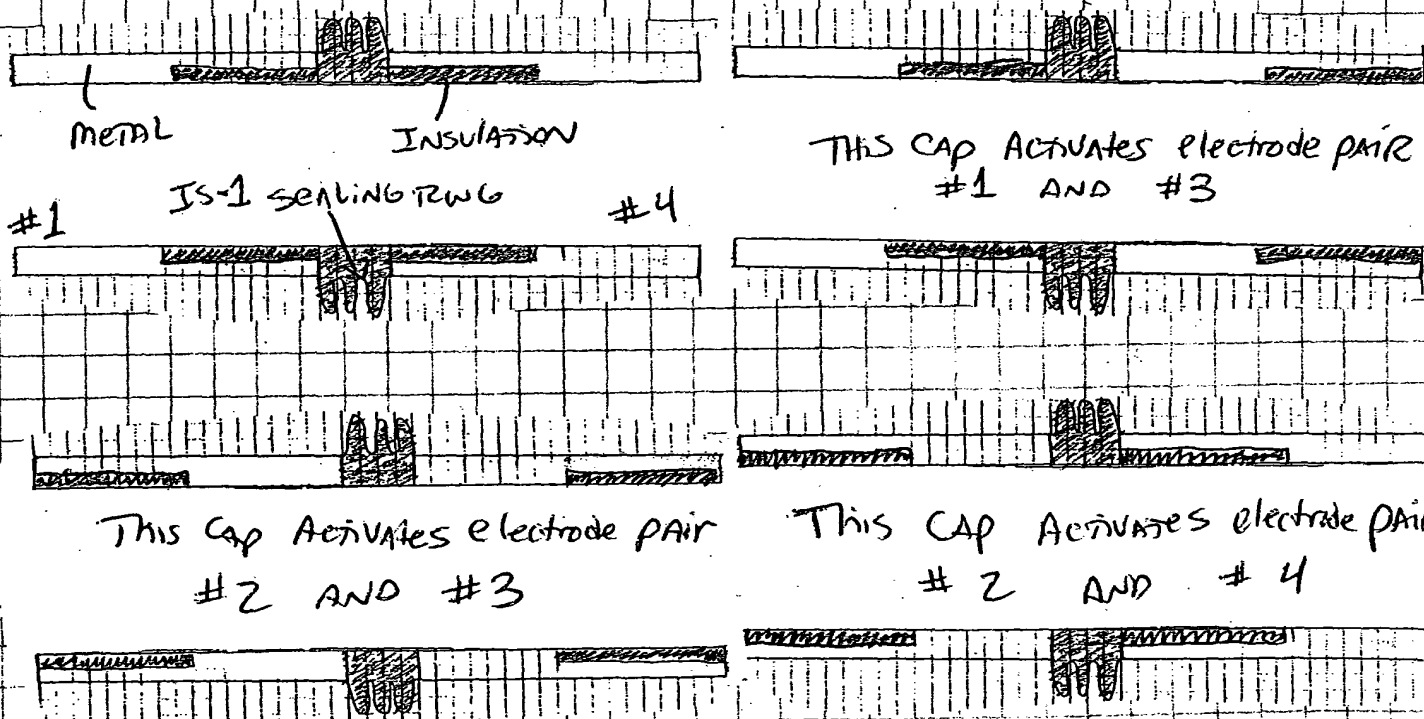


FIGURE 3: METALLIC IS-1 CAPS. EACH CAP WILL PROVIDE A DIFFERENT electrode pair TO BE ACTIVE

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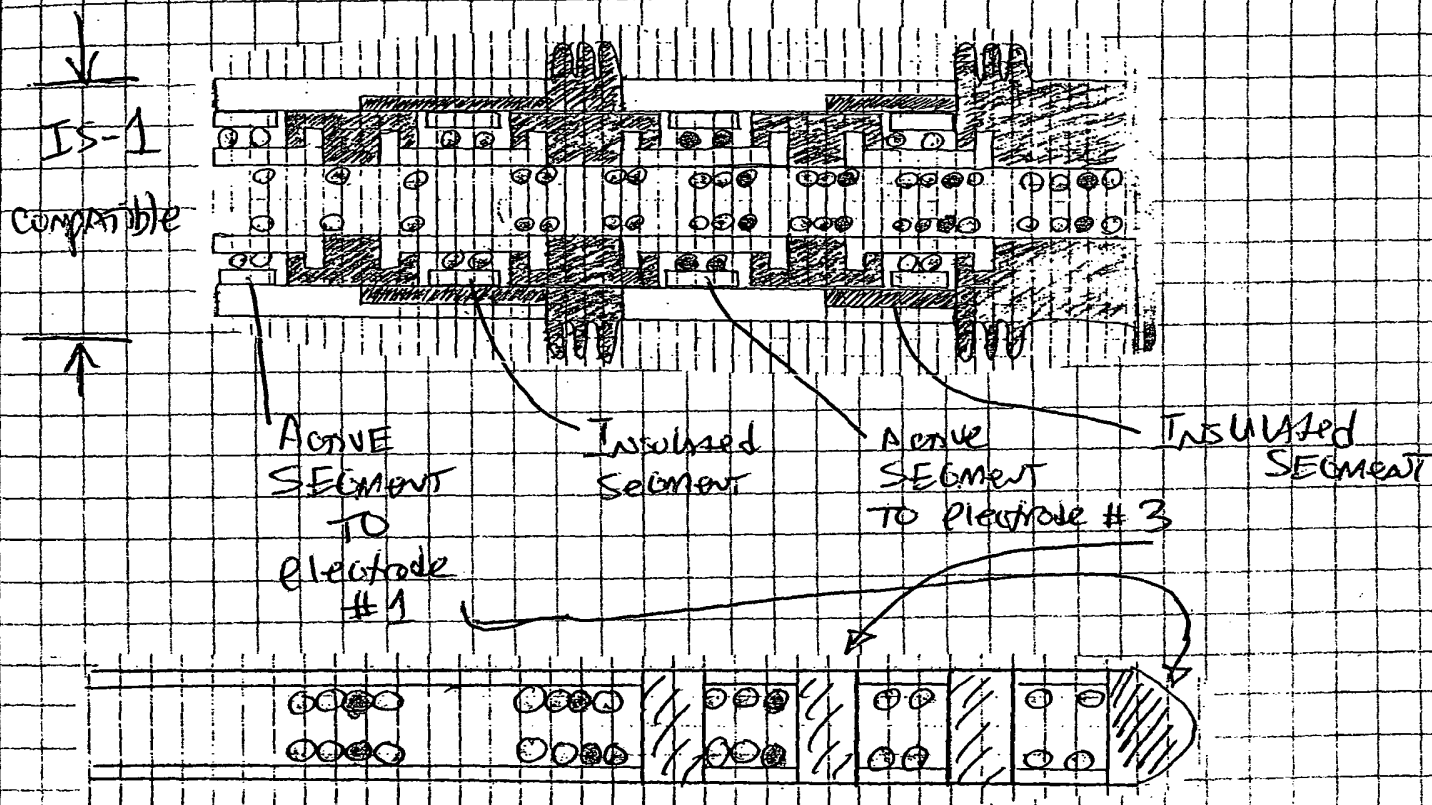
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19 July 02

From Page N

ONCE THE IS-1 CONNECTOR PIN CAP IS ~~STAY~~ ^{DOWN} SLID
 OVER THE SEGMENTED CONNECTOR PIN TWO OF
 SEGMENTS ARE INSULATED WHILE TWO OF THE
 SEGMENTS MAKE CONTACT WITH THE METALLIC PIN CAP.

THIS ASSEMBLY IS NOW PROPERLY SIZED FOR ANY
 IS-1 COMPASSIBLE GENERATOR. IT WILL FUNCTION AS
 A BIPOLAR LEAD WITHOUT ANY CHANGES REQUIRED TO
 STANDARD ICG HEADER OR CIRCUIT DESIGN.



IF A different bipole IS REQUIRED AFTER IMPLANT, THE IS-1
 CONNECTOR PIN CAP CAN BE EXCHANGED FOR A different
 ONE WHICH SELECTS AN ALTERNATE BIPole.
 Four PAIRS ARE possible unless THE ICG CAN BE PROGRAMMED
 TO "REVERSE POLARITY" IN WHICH EIGHT OPTIONS ARE AVAILABLE

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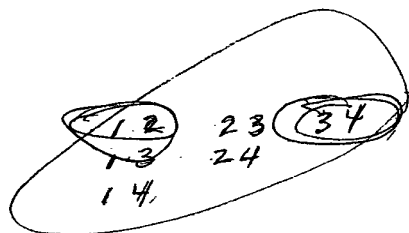
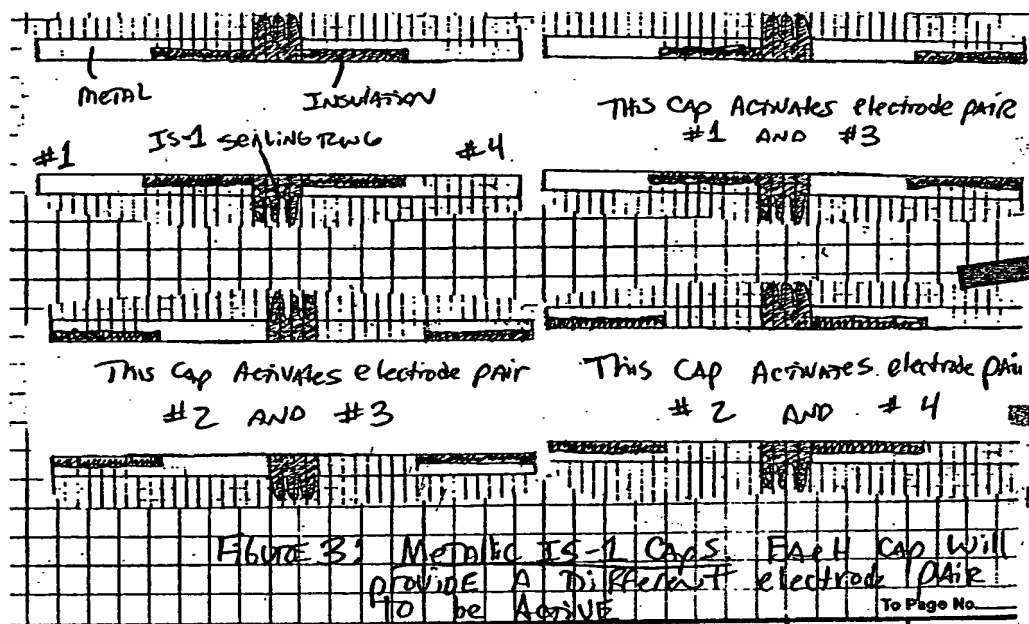
Date

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To Page No.

P-11138 "Pacing Lead With Multiple Electrodes Having One IS-1 Compatible Connector Pin" Hine, Sommer, Gurley

Describes an adaptor cap which selects an anode to be used with multi-anode leads. The cap allows the lead to be used with an IS-1 connector.

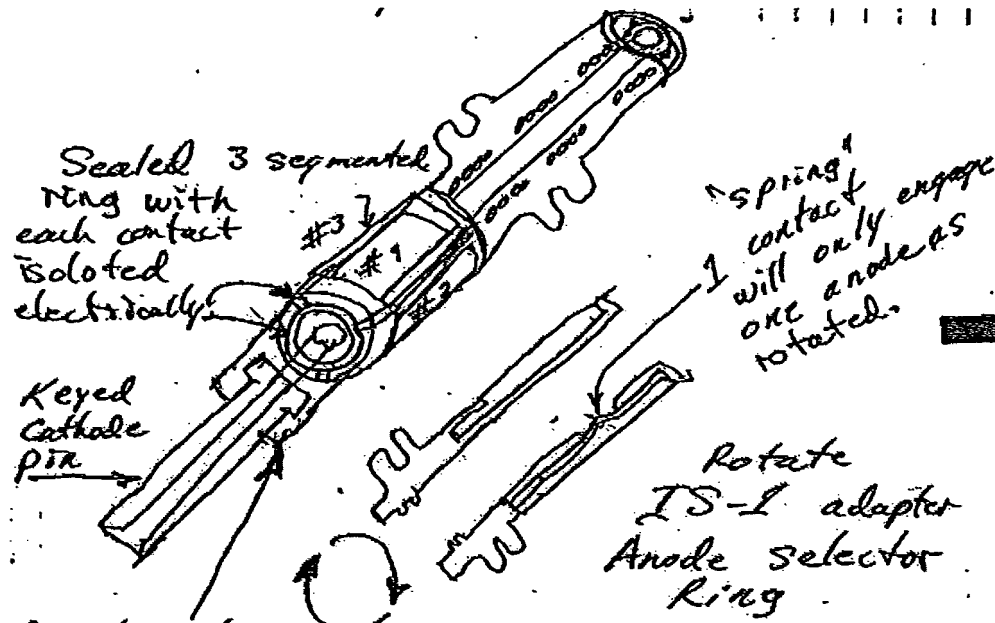


P-11138 continued

Prior Art

1. P-11139 "Selectable Electrical Connection" Sommer, Hine

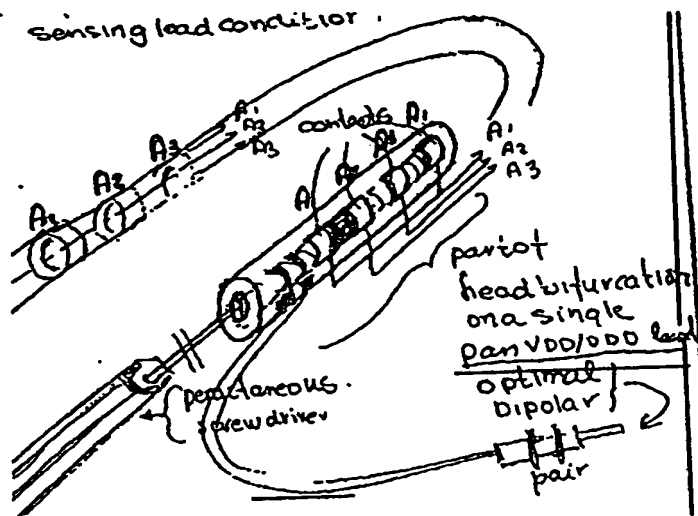
Describes an IS-1 adaptor which uses a spring-mounted contact to select between multiple anodes on a lead. This allows multi anode leads to be used with a standard IS-1 connector block.



P-11138 continued

2. P-3563. "A Percutaneous Switch To Select Optimal Sensing Lead Conditions" Bakels et al

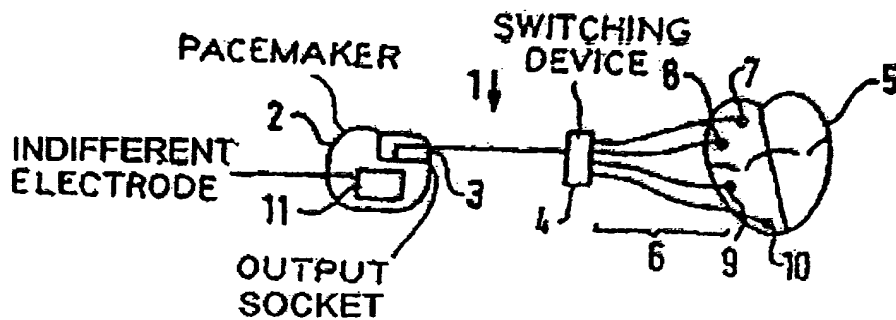
Percutaneously adjustable rotating cam selects bipolar lead connections from multiple atrial electrode.



P-11138 continued

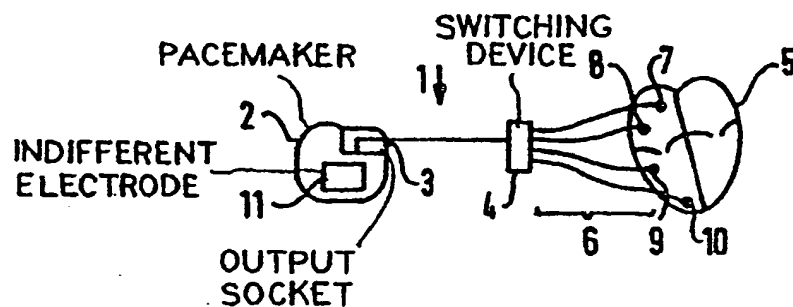
3. P-4227 "Intermediate In-Line Programmable Multi-Channel Selector For Multi-Site Sequential Pacing" Struble

A multichannel selector is disclosed that controls/directs pacing stimulus to the correct lead system. Device is incorporated between pacer and lead systems.



4. 5,423,873 "Device For Stimulating Living Tissue" Neubauer et al (Siemens Elema AB)

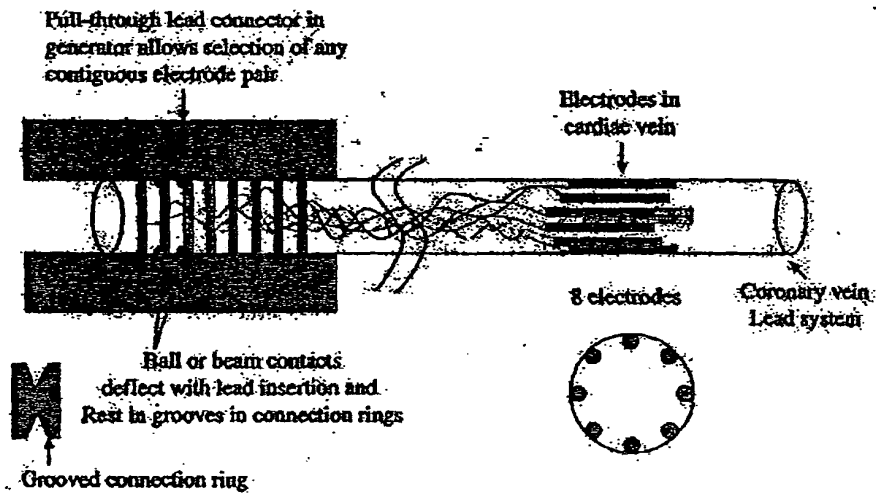
Describes a programmable switching device placed between the IPG and lead.



P-11138 continued

5. P-9797 "Focused Delivery Coronary Venous Electrode" Duffin, Brostrom

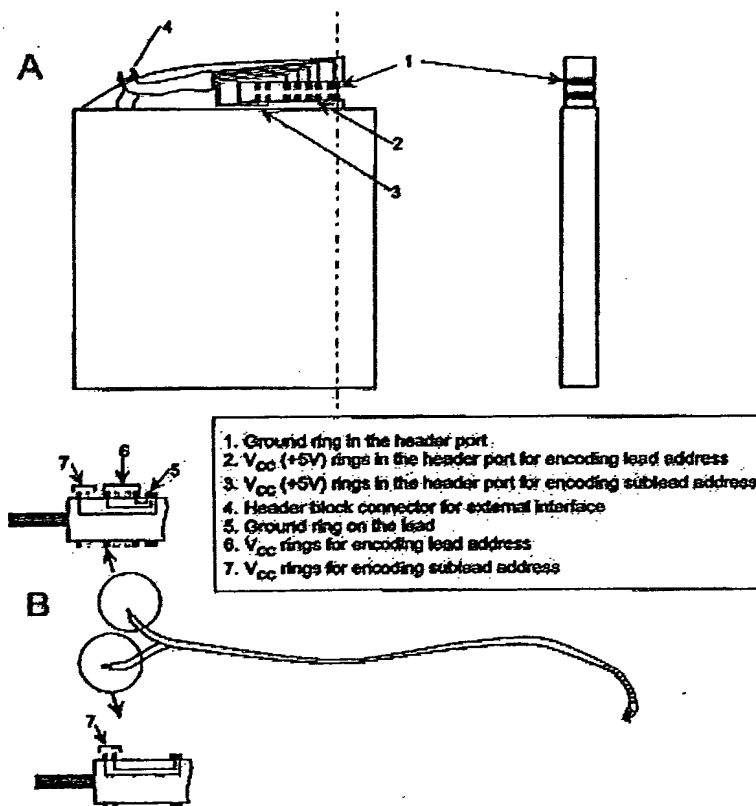
Connects an output circuit to a selected pair of electrodes chosen by the position of the lead connector pin within the connector block.



P-11138 continued

6. P-9569 "Automatic Lead Identification System for ICDs" Sharma, Whitman, Bonner

Lead identification based upon a unique binary code set via proximal lead ring electrodes.



P-11138 continued

7. P-9124 "Multiple Electrode-Array with Incorporated Switch to Select Stimulation Site" Heynen, Lokhoff, Houben

Epicardial electrode array that may have electrode configuration selected/controlled by a coded signal from an implanted device or external box.

